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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,698	11/27/2001	William B.S. Pressly Sr.	14112-187003	2662

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02/25/2003

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EXAMINER

THOMPSON, KATHRYN L

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,698

Applicant(s)

PRESSLY SR. ET AL.

Examiner

Kathryn L Thompson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

This species restriction is regarding new claims 14-18 that Applicant added in his Amendment.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species (A): Figure 1; Species (B): Figure 31; and Species (C): Figure 39.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

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Species (A): Figure 1, Claims 14-16; Species (B): Figure 31, Claim 17; and Species (C): Figure 39, Claim 18.

The following claim(s) are generic: there are no generic claims.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Species (B) comprises bars, and Species (C) comprises a shelf.

During a telephone conversation with Mr. Ben Mullinak on February 21, 2003, a provisional election was made without traverse to prosecute the invention of Species (A), claims 14-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17 and 18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Regarding Claim 14, the, "at least one support member having a first end and a second end," and, "an edge defined by a needle assembly," were not found by the Examiner in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "said needle head" in Line 2

. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Pressly, Sr. et al (US 5,613,952). Pressly, Sr. et al teaches an interchangeable needle (3), an elongated barrel having first and second ends, the interchangeable needle attached to a first end of the barrel (5), a plunger sized and shaped to be received in the second end of the barrel and to be movable therein (7), a movable base adapted to releasably constrain the needle (11), a spring (21) at least partially compressed, said spring positioned entirely within the barrel (See Figure 2) and surrounding a portion of a base of a needle hub (See Figure 1), said spring adapted to bias the interchangeable needle within the barrel and wherein the plunger is moved within the barrel applying force to the interchangeable needle and causing the spring to retract the interchangeable needle

within the plunger, retainer catches (31) having flexible supports/support members on the base, an integral sacrificial seal (10) on the base, a rupturable web (79) on one end through which the needle hub is forced when the spring triggers, a circular groove on the needle hub for guiding the needle head into the syringe, a needle catch (49) in the plunger, a needle guard (12) releasably affixing the needle and needle head therein, a method for operating a safety syringe with an interchangeable needle, and a process of forming the interchangeable needle safety syringe.

Claims 1-4, 6, and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Redfern et al (US 5,843,034). Redfern et al teaches an interchangeable needle (12), an elongated barrel having first and second ends, the interchangeable needle attached to a first end of the barrel (14), a plunger sized and shaped to be received in the second end of the barrel and to be movable therein (16), a rupturable web (66), a movable base adapted to releasably constrain the needle (20), a spring (18) at least partially compressed, said spring positioned entirely within the barrel and surrounding a portion of a base of a needle hub (See Figure 2), said spring adapted to bias the interchangeable needle within the barrel, retainer catches (64), an integral sacrificial seal (50) on the base, an interchangeable needle head (22), a needle hub (76), a needle catch(42) (Column 4, Lines 63-65) in the plunger, a needle guard (24) releasably affixing the needle and needle head therein, and a method for operating a safety syringe with an interchangeable needle.

Claim Rejections -35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Redfern et al in view of Jentzen (US 5,902,269). Redfern et al teaches all of the claimed limitation except an interchangeable needle head portion with threads and attaching the interchangeable needle head by threading it to the syringe. Jentzen teaches an interchangeable needle head portion with threads and attaching the interchangeable needle head by threading it to the syringe (Column 4, Lines 1-3). It would have been obvious to one with ordinary skill in the art to use the teachings of Jentzen to modify the invention of Redfern in order to attach the interchangeable needle portion to the syringe, since it is well known in the art that threading is a way of attaching the claimed elements.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Redfern et al in view of Pressly, Sr. et al ('952). Redfern et al teaches all of the claimed limitations except revealing a biohazard label viewable through the barrel. Pressly, Sr. et al teaches revealing a biohazard label viewable through the barrel (Column 9, Lines 63-66). Pressly, Sr. et al discloses that a biohazard label provides the advantage of

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alerting the user of the syringe that the syringe has been used and represents a potential biohazard (Column 2, Lines 46-49). It would be obvious to one with ordinary skill in the art to use the teachings of Pressly, Sr. et al to modify the invention of Redfern et al in order to create a syringe that indicates when it has been used and is a potential biohazard.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPO 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPO 761 (CCPA 1982); *In re Voget* 422 F.2d 438, 164 USPO 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are rejected under the judicially created doctrine of obviousnesstype double patenting as being unpatentable over claims 1, 6, 7, 12, and 13 of U.S. Patent No. 5,211,629. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims in the patent and the instant application claim a safety syringe with the same features.

Response to Arguments

Applicant's arguments filed on December 2, 2002, have been fully considered but they are not persuasive. Applicant states that, "...Pressly et al '952 reference fails to teach an interchangeable needle...". Examiner respectfully disagrees. Examiner believes Pressly et al does indeed teach an interchangeable needle. It is clear that the needle (Figure 7) moves (Figures 1 and 2) and thus is capable of being interchanged. The fact that the base is deformable, according to the specification, is further evidence that the needle is capable of being removed and thus is interchangeable.

Applicant states that, "The structure 22 of Redfern does not provide for a moveable base..." Examiner would like to bring Applicant's attention to Page 3 of the Office Action dated May 23, 2002. In the 102(b) rejection anticipated by Redfern et al, Examiner interpreted the movable base as being reference number 20 in Redfern et al, not reference number 22, as indicated by Applicant on Page 6 of Applicant's response. Applicant maintains that reference number 20 of Redfern which is attached to the plunger 16 does indeed meet the claim limitations of Applicant's movable base.

Regarding newly added Claim 14, Applicant states on Page 8 of his response that, "Support for the subject matter in claims 14 and 15 may be seen in reference to the support members 21...as described in the specification on Page 8, lines 12-16 and page 9, lines 20-24." Examiner respectfully disagrees. Examiner found no disclosure of the support members as indicated by Applicant. Likewise, regarding

newly added Claim 16, Examiner did not find support in the specification on Page 2, Lines 1-2, as indicated by Applicant.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Thompson whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

KLT *KLT*
February 23, 2003

Michael J. Hayes
MICHAEL J. HAYES
PRIMARY EXAMINER